



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 112, 117, and 507

[Docket Nos. FDA-2011-N-0920, FDA-2011-N-0921, FDA-2011-N-0922, and FDA-2011-N-0143]

RIN 0910-AG36, RIN 0910-AG35, RIN 0910-AG10, and RIN 0910-AG64

Food and Drug Administration Food Safety Modernization Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed revisions to four rules originally proposed in 2013 to implement the FDA Food Safety Modernization Act (FSMA). In response to the comments received on these foundational FSMA proposed rules, FDA issued supplemental notices of proposed rulemaking that propose significant changes to four of the proposed rules including: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventive Controls for Animal Food); and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (Foreign Supplier Verification Programs). The purpose of the public meeting is to solicit oral stakeholder and public comments on the new content of the supplemental proposed rules and to inform the public about the rulemaking process (including

how to submit comments, data, and other information to the rulemaking dockets), and to respond to questions about the supplemental proposed rules.

DATES: See section II, “How to Participate in the Public Meeting,” in the SUPPLEMENTARY INFORMATION section of this document for the date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA’s Division of Dockets Management.

ADDRESSES: See section II, “How to Participate in the Public Meeting,” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting; to register by telephone; or to submit a notice of participation by mail, FAX, or email: Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott St., Suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: ctreece@planningprofessionals.com.

For general questions about the meeting; to request an opportunity to make an oral presentation at the public meeting; to submit the full text, comprehensive outline, or summary of an oral presentation; or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Public Law 111-353) was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the U.S. food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act to establish the foundation of

a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring preventive controls for human food and animal food, setting standards for produce safety, and requiring importers to verify that their foreign suppliers produce food that is as safe as food produced in the United States.

FSMA was the first major legislative reform of FDA's food safety authorities in more than 70 years, even though FDA has increased the focus of its food safety efforts on prevention over the past several years. Since January 2013, FDA has proposed seven foundational rules to implement FSMA: Produce Safety, Preventive Controls for Human Food, Preventive Controls for Animal Food, Foreign Supplier Verification Programs, Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, Focused Mitigation Strategies to Protect Food Against Intentional Adulteration, and Sanitary Transportation of Human and Animal Food. FDA conducted extensive outreach to industry, growers, academia, consumer groups, tribal governments, and the Agency's counterparts at the Federal, State and local levels, and received thousands of comments on the proposals.

In response to the comments received on some of the foundational FSMA proposed rules, which FDA continues to review, FDA issued supplemental notices of proposed rulemaking that propose significant changes to four of the proposed rules: Preventive Controls for Human Food, Produce Safety, Preventive Controls for Animal Food, and Foreign Supplier Verification Programs. FDA's proposed changes are intended to provide more flexible, practical, and targeted approaches to ensuring a safe food supply system.

In the Federal Register of September 29, 2014 (79 FR 58523, 58433, 58475, and 58573), FDA announced the reopening of these four dockets so that the public can review the supplemental proposed rules and submit comments to the Agency. The Agency is accepting

comments on the revised provisions of all four proposed rules until December 15, 2014. No additional comments will be accepted on the original proposed rules.

FDA is announcing a public meeting entitled “Food and Drug Administration Food Safety Modernization Act” so that the food industry, consumers, foreign governments, and other stakeholders can evaluate and comment on the supplemental proposals. The meeting is intended to facilitate and support the supplemental proposed rules’ evaluation and commenting process.

For information on the supplemental proposed rules and related fact sheets, see FDA’s FSMA Web page located at <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>.

II. How to Participate in the Public Meeting

FDA is holding the public meeting on the supplemental proposed rules to inform the public about the rulemaking process, including how to submit comments, data, and other information to the rulemaking dockets; to respond to questions about the supplemental proposed rules; and to provide an opportunity for interested persons to make oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated. Live Webcasting of the event is also being offered through the registration process.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request and to provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and the number of supplemental proposals being addressed at the public meeting, time for making public comment is necessarily limited. FDA is allocating 3 minutes to each speaker to

make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the relevant rulemaking. All relevant data and documentation should be submitted with the comments to the appropriate docket (Docket Nos. FDA-2011-N-0920, FDA-2011-N-0921, FDA-2011-N-0922, and FDA-2011-N-0143).

Table 1 of this document provides information on participation in the public meeting:

Table 1.--Information on Participation in the Meeting and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Public meeting	November 13, 2014	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	Wiley Building, 5100 Paint Branch Pkwy., College Park, MD 20740	Onsite registration from 8 a.m.-8:30 a.m.
Advance registration	By November 7, 2014	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible. ¹	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make an oral presentation	By October 27, 2014	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm ²		Requests made on the day of the meeting to make an oral presentation will be granted only if time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Request special accommodations due to a disability	By October 27, 2014	Juanita Yates, email: Juanita.yates@fda.hhs.gov	See FOR FURTHER INFORMATION CONTACT	
Submit electronic or written comments	By December 15, 2014	Docket Nos. FDA-2011-N-0920, FDA-2011-N-0921, FDA-2011-N-0922, and FDA-2011-N-0143; http://www.regulations.gov	Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852	

¹ You may also register via email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott St., Suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: ctreece@planningprofessionals.com. Onsite registration will also be available.

² You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the relevant rulemaking and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record for each of the rulemakings. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and at FDA's FSMA Web site at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be live Webcasting the event. When available, the Webcast video recording of the public meeting will be accessible at FDA's FSMA Web site at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm>.

Dated: October 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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